DECLARATION OF LIEUTENANT CHAD COPPIN

Pursuant to 28 U.S.C. §1746, I, Chad Coppin, declare as follows:

1. My name is Chad Coppin. I am over 18 years of age and have personal knowledge of and am competent to testify on the matters stated herein.

2. I make this declaration in support of my challenge to Defendants' Department of Defense, Department of Homeland Security, and the U.S. Coast Guard mandates requiring that I be vaccinated against COVID-19. All statements made in this Declaration are true to the best of my own personal knowledge.

3. I currently reside at Juneau, Alaska. My home of record and where I am domiciled is Bellingham, Whatcom County, Washington.

4. On August 15, 2022, I, along with several other military whistleblowers, submitted to all Members of Congress, pursuant to the Military Whistleblower Protection Act, 10 U.S.C. § 1034, a "Memorandum for All Members of Congress from Concerned Service Members" ("Military Whistleblower Memorandum"). *See* Attach. 1. In that letter, we detailed the Defendants' systemic violations of service members' rights to refuse Emergency Use Authorization ("EUA") products. We also submitted evidence demonstrating that the new "Comirnaty-labeled" products offered by Defendants have not been licensed by the Food and Drug Administration ("FDA") and are instead EUA products. In particular, we provided information demonstrating that the "Comirnaty-labeled" vaccine labeling identified it as being from Lot Number FW1331; a Pfizer representative informed us that Lot FW1331 was manufactured in France, rather than the FDA-approved location in Belgium; and the Centers for Disease Control and Prevention ("CDC") website lists Lot FW1331 as an EUA product. *See* Attach. 1, Military Whistleblower Memorandum, ¶¶ 14-15. *See also* Attach. 2, Declaration of 1LT. Mark C. Bashaw

5. On August 26, 2022, the FDA responded to the Military Whistleblower Memorandum in a related proceeding. *See* Attach. 3, *Coker v. Austin*, NDFL Case No. 3:21-cv-1211-AW-HTC, ECF 108 & 108-1 (Aug. 26, 2022) ("FDA Supplemental Declaration"). The FDA Supplemental Declaration includes an April 7, 2022 "Lot Release" letter for Pfizer Lot Number FW1331 that the FDA claims demonstrates that the "Comirnaty-labeled" product offered by Defendants is in fact an FDA-licensed product because it was manufactured in Kalamazoo, Michigan, on January 28, 2022. The FDA Supplemental Declaration does not address, or attempt to rebut, the evidence that the CDC website lists Lot FW1331 as an EUA-only lot.

6. I submit this declaration to refute the FDA's claims and to provide additional evidence showing that the Lot FW1331 is an EUA product as claimed in the Military Whistleblower Memorandum.

7. To date, the FDA has approved three Biologics License Applications for three different formulations and/or manufacturing locations for Pfizer's COVID-19 vaccines (*i.e.*, Comirnaty). The timeline and details for each approval are as follows:

- August 23, 2021: FDA approves the BLA for the original formulation (Purple Cap), Submission Tracking Number ("STN") BL 125742/0, for ages 16 and over to be manufactured in Puurs, Belgium, and Kalamzoo, Michigan. *See* Attach. 4 at 1.
- December 16, 2021: FDA approves the BLA for the Tris/Sucrose formulation (Gray Cap), STN BL 125742/36, for ages 16 and over to be manufactured in Puurs, Belgium (only). *See* Attach. 5 at 1.
- July 8, 2022: FDA approves the BLA for the Tris/Sucrose formulation (Gray Cap), STN BL 125742/45, for ages 12-15 to be manufactured in Puurs, Belgium, Kalamazoo, Michigan, and McPherson, Kansas. *See* Attach. 6 at 1.

8. The April 7, 2022 FDA Lot Release Letter for Lot FW1331 is identified using STN 125742/36 for the December 16, 2021 BLA for the Tris/Sucrose formulation (Gray Cap). The FDA December 16, 2021 BLA approval permits this formulation to be manufactured ***only*** in Puurs, Belgium. The Kalamazoo, Michigan facility was not licensed nor approved to manufacture the

Tris/Sucrose formulation on January 28, 2022 (manufacturing date) or on April 7, 2022 (the lot release date). The Kalamazoo, Michigan facility also was not licensed nor BLA-approved as of June 10, 2022, the date when the Defendant Coast Guard received a shipment of "Comirnaty-labeled" vaccines that I personally inspected, as set forth in the Military Whistleblower Memorandum.

I make this declaration under penalty of perjury, it is true and accurate to the best of my ability, and it represents the testimony I would give if called upon to testify in a court of law.

September 5, 2022

Chad Coppin

EXHIBIT 2

United States Senate
WASHINGTON, DC 20510

August 18, 2022

The Honorable Lloyd J. Austin III
Secretary of Defense
U.S. Department of Defense

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration

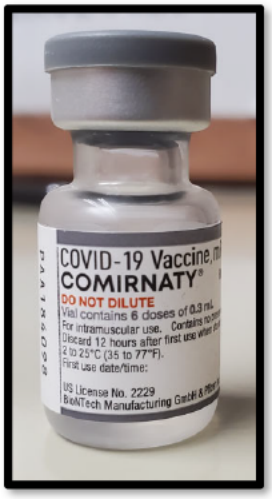
Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention

Dear Secretary Austin, Commissioner Califf, and Director Walensky:

Nine Department of Defense (DoD) whistleblowers recently provided my office with information that raises questions about the manufacturing and labeling of COVID-19 vaccines distributed to service members.[1] These new whistleblower allegations must be fully addressed by DoD, the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).

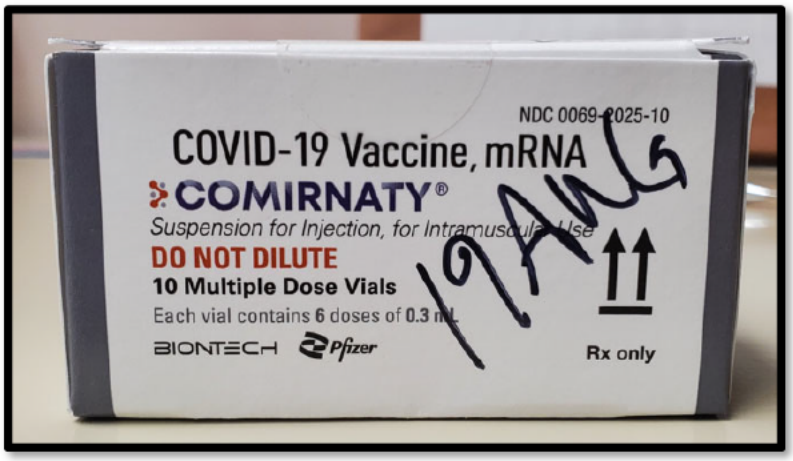
Lt. Chad Coppin, who is a commissioned officer in the U.S. Coast Guard, disclosed that on June 10, 2022, his base located in Juneau, Alaska received "a shipment of 60 Comirnaty vials packaged in six boxes of ten vials."[2] These vials included the vaccine lot number FW1331.[3] Lt. Coppin noted that, "[p]rior to this date, only emergency use authorization shots [had] been available[.]"[4] Lt. Coppin provided my office with pictures of one of the Comirnaty vials and boxes his base received:

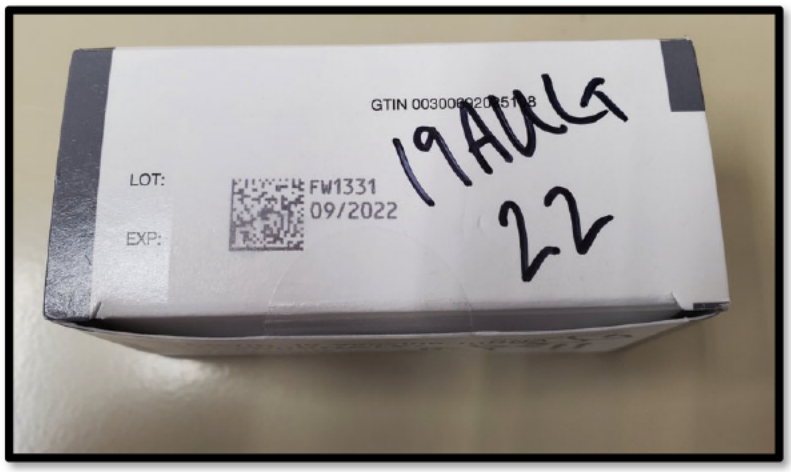
Pictures of Comirnaty Vial (taken on June 10, 2022)



[1] Letter from nine Dep't of Defense whistleblowers, Aug. 15, 2022 (enclosed).
[2] Chad Coppin disclosure to Sen. Ron Johnson (on file).
[3] *Id.*
[4] *Id.*

Pictures of Comirnaty Box (taken on June 10, 2022)





Lt. Coppin reported that he attempted to determine the shipping and manufacturing locations of these specific vaccines.[5] He explained to my office that the medical staff at his base informed him that the vials were shipped from Ft. Detrick in Maryland.[6] Lt. Coppin stated that he contacted Ft. Detrick to ask about the manufacturing location of the vials and was told that these vials came from a "Pfizer plant" located in Kalamazoo, Michigan.[7]

Lt. Coppin then called Pfizer directly to ask about the manufacturing location of the specific vaccine lot number for these vials: FW1331.[8] A Pfizer customer service representative apparently told him that this lot was manufactured in France on January 28, 2022 and expires on December 31, 2022.[9] Lt. Coppin disclosed to my office that, "The significance of the France manufacturing location is that it is not an authorized manufacturing location as per the FDA's Comirnaty [Biologics License Application (BLA)] Supplement Approval letter dated December 16, 2021."[10] That letter approved a "30 microgram dose formulation (Tris/Sucrose) of

[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*

Comirnaty" to be manufactured at the "Pfizer Manufacturing Belgium NV, Purrs, Belgium facility."[11] Any Comirnaty vaccine lots that are manufactured outside of the FDA-approved manufacturing locations and distributed to U.S citizens raises significant legal and health-related concerns.

In addition to the lack of clarity relating to the manufacturing location of vaccine lot FW1331, another DoD whistleblower raised questions about whether this specific vaccine lot is mislabeled as "Comirnaty." 1Lt. Mark Bashaw, who is a commissioned officer in the U.S. Army, found that the lot number contained on these "Comirnaty" vials—FW1331—matched a lot number on a CDC database listing Emergency Use Authorization (EUA) vaccine lots.[12]

According to CDC, this database, which is called the COVID-19 Vaccine Lot Number and Expiration Date Report, "contain[s] all lots for COVID-19 vaccines made available under [EUA] for distribution in the United States."[13] 1Lt. Bashaw disclosed to my office that he downloaded this database and found that it included vaccine lot FW1331.[14] DoD, FDA, and CDC must provide a thorough explanation for why a vaccine lot with the "Comirnaty" label would be listed on a database that is meant to display vaccine lots associated with the EUA.

Lt. Coppin, 1Lt. Bashaw, and the additional seven DoD whistleblowers who brought this information to my attention have exercised their right to talk to Congress. Any retaliatory actions taken against these individuals will not be tolerated and will be investigated immediately. DoD, FDA, and CDC owe our service members complete transparency regarding the COVID-19 vaccines that the Biden administration has forced upon them. With this in mind, I request that you provide the following information:

1. Was vaccine lot FW1331 manufactured at the Pfizer facility located in Belgium? If not, why not?

2. Why is vaccine lot FW1331, which is labeled "Comirnaty," listed on a CDC database ("COVID-19 Vaccine Lot Number and Expiration Date Report") for EUA vaccine lots?

3. Was vaccine lot FW1331 created under the EUA? If so, why is it labeled "Comirnaty"?

4. Please identify the vaccine lot numbers, in addition to FW1331, that are labeled "Comirnaty" and have been distributed to U.S. military bases *and* are also listed on CDC's "COVID-19 Vaccine Lot Number and Expiration Date Report."

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[11] Letter from Jerry Weir, Food and Drug Administration, to Amit Patel, Pfizer Inc , Dec. 16, 2021, https://www.fda.gov/media/154939/download.
[12] Mark Bashaw disclosure (on file).
[13] COVID-19 Vaccine Lot Number and Expiration Date Report, Centers for Disease Control and Prevention, https://vaccinecodeset.cdc.gov/LotNumber.
[14] Mark Bashaw disclosure (on file).

Please provide this information as soon as possible but no later than September 1, 2022. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
United States Senator

cc: The Honorable Sean O'Donnell
Acting Inspector General
Department of Defense

The Honorable Christi Grimm
Inspector General
Department of Health and Human Services

Enclosure

Enclosure

15 August 2022

Memorandum for all Members of Congress from Concerned Service Members

Subject: Whistleblower Report of Illegal Department of Defense Activity

Encl: (1) Pfizer Announcement that Comirnaty will not be produced, NIH Website, 13 Sep 2021
(2) Defense Health Agency Freedom of Information Act Response 21-00359, 20 Apr 2022
(3) Assistant Secretary of Defense Health Affairs, Mandatory Vaccination of Service Members using Pfizer-BioNTech and Comirnaty COVID-19 Vaccines, 14 Sep 2021
(4) Unsigned Proposed Mandatory Vaccination of Service Members Replacement Memo submitted to Dr. Terry Adirim on 20 Oct, 2021
(5) Component Comment Review Matrix for Proposed Military Vaccination of Service Members Memorandum, Submitted 29 Oct 2021
(6) Coker v. Austin, USDC Northern District of Florida, Document 88-1, 20 May 2022
(7) Military Whistleblower Photographs of "Comirnaty-Labeled" vaccine product taken at USCG Sector Juneau, AK, 10 Jun 2022
(8) CDC COVID-19 Vaccine Lot Number and Expiration Date Database
(9) Declaration of 1LT Mark C. Bashaw, US Army, 4 Aug 2022
(10) FDA Comirnaty Supplement Approval, 16 Dec 2021
(11) Declaration of LT Chad R. Coppin, USCG, 30 Jul 2022

1. The undersigned hereby submit this report under the Military Whistleblower Protection Act (10 USC § 1034) as duty requires us to advocate for the rights of all American citizens and for the rights of service members across all branches of the Armed Forces. Pursuant to 28 USC § 1746, the undersigned declare under penalty of perjury as follows:

2. Since 24 August 2021, the Department of Defense (DoD) has unlawfully administered Emergency Use Authorized (EUA) products (i.e., products authorized but not approved by the Food and Drug Administration (FDA)) *as if* they were fully licensed FDA approved products. Military members have not been allowed to exercise their legal right to refuse EUA products, despite the Department of Justice's (DOJ) assertion that "Comirnaty-labeled" vaccines only became available for the DoD to order on 20 May 2022. Evidence also exists that the new "Comirnaty-labeled" products are not FDA approved in accordance with applicable laws.

3. Americans never lose the right to legally refuse an EUA product. EUA law 21 USC § 360bbb imposes significant responsibilities upon the government to inform Americans of their rights. The only exception to the government's duty to inform citizens of their rights is in a narrowly defined presidential waiver process for the military per 10 USC §1107a. This exception only waives the required condition that service members be informed of their right to refuse an EUA product. The 105th Congress passed 10 USC § 1107 into law as part of the Fiscal Year 1998 National Defense Authorization Act as a result of the injuries sustained by Gulf War veterans due to forced administration of investigational new drugs. This was quickly followed by the passage of 10 USC § 1107a, which specifically addressed use of EUA products. Similar to the Constitutional violation of failing to provide a suspect their Miranda Rights, not informing a potential recipient of their right to accept or decline an EUA product, either by presidential waiver or by omission, does not remove the underlying rights protected by statute and the Constitution.

4. Prior to the administration of an EUA product, the recipient is required to be informed inter alia of the option to accept or refuse administration of the EUA product, as codified in 21 USC § 360bbb-3(e)(1)(A)(II)(iii). This right is a required condition that the Secretary of Health and Human Services (HHS) shall include for the authorization of any unapproved product covered by an emergency declaration. This means that by law, no one can mandate EUA products and the Government must inform recipients of their right to refuse. Service members are not being informed of the option to refuse administration of EUA products, nor are they provided with any other required information such as the risks associated with the product. Instead, military leadership is coercing service members into accepting administration of EUA products through unlawful threats against their careers and livelihoods. The failure of numerous appeals to leadership, Equal Opportunity complaints, Article 138 requests for redress, Inspector General complaints, and Congressional inquiries filed by the undersigned and those similarly situated, indicate that the military has no intention of following the law or their own regulations. Accordingly, Congress must act swiftly to end this unlawfulness and preserve the rights, readiness, and character of the military.

5. The law justly enshrines the principle that where there is risk, there must be legally effective informed consent. There must be full disclosure of relevant information and it must be absent coercion and undue influence. For risky medical products, like EUA pandemic products, Congress provides complete liability protection against any claim of loss for all persons and entities who are involved in the manufacture, distribution, planning, or administration of those products. 42 USC § 247d-6d(a)2(A) defines loss very broadly, listing everything from death to fear of emotional injury to property loss from business interruptions. For clarity, persons and entities covered by liability protections include product developers, manufacturers, and administrators (health care personnel), as well as all related governmental personnel at the local, state, and federal levels, including members of Congress and the DoD. Accepting administration of an emergency use product means the individual accepts all the health, legal, financial, and medical risks arising from that product.

6. Injured recipients (or their families, in the event of death) who voluntarily received an EUA product only have one legal method to recoup losses: by filing a compensation claim through the Countermeasure Injury Compensation Program (CICP) as per 42 USC § 247d-6e. To date, there are 8,808 total COVID-19 related claims in the CICP. Claims of loss typically have a benefit cap of $379,000, however HHS has not granted a single dollar to those 8,808 claimants.[1] Due to complete liability protections during declared emergencies, neither the Executive Branch of government nor any manufacturer, developer, producer, or administrator of covered products have any incentive to ensure the safety or efficacy of the products they are providing. The pandemic demonstrated that without congressional action the executive branch and administrative state will continue to baselessly declare and extend emergencies, exercising powers that exceed federal authority.

7. In a memorandum issued on 9 August 2021, Secretary of Defense (SECDEF) Lloyd Austin indicated his comprehension of EUA law, stating, "I will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the U.S. Food and Drug Administration (FDA) licensure, whichever comes first."[2] On 23 August 2021, the FDA approved

[1] https://www hrsa.gov/cicp/cicp-data#table-1, accessed 10 Aug 2022
[2] https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF, accessed 10 Aug 2022

(fully licensed) the first COVID-19 vaccine under the trade name Comirnaty®. Of interest, the FDA ended its legal marketing status that same day.[3] The next day, SECDEF issued a memorandum that stated "[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."[4] Shortly thereafter, in a posting on the National Institute of Health website, enclosure (1), Pfizer announced they would not produce any of the licensed product "over the next few months while EUA authorized product is still available and being made available for U.S. distribution." For nine months afterwards, this lack of fully licensed product has been confirmed by hundreds of service members, who have provided military leadership hundreds of complaints, many with photo evidence, indicating all vials found in Military Treatment Facilities were EUA products. A Freedom of Information Act (FOIA) response from the Defense Health Agency (DHA) in April 2022, enclosure (2), confirmed DHA had no record of "Comirnaty" COVID-19 vaccines being ordered, received, in stock, available, or administered to any service member by any service branch (Army, Navy, Marine Corps, Air Force, or Coast Guard).

8. Subordinate commanders failed to adhere to both the law and to SECDEF guidance regarding licensure of products. Military commanders ordered service members to become vaccinated against COVID-19 without consideration for the EUA status of available vaccines. The mandate also set an unrealistic policy of 100% vaccination. DoD instructions clearly provide for religious accommodation and medical exceptions to vaccines, nearly 100% of which are being systematically disapproved. Federal courts have acknowledged that the military's implementation of these instructions have been so egregious that numerous injunctions have been levied against the DOD for violating the Constitution, Religious Freedom Restoration Act, and DoD policy.

9. The DoD induced confusion by publishing memoranda asserting that the FDA-approved Comirnaty® could be used interchangeably with EUA products. Assistant Secretary of Defense for Health Affairs (ASD HA), Dr. Terry Adirim, wrote a 14 September 2021 memorandum, enclosure (3), stating "these two vaccines are interchangeable and DoD health care providers should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." In her memorandum, she cited the FDA's Q&A website to justify use of EUA Pfizer-BioNTech vaccines in lieu of Comirnaty®. The website provided medical advice regarding the use of the EUA product to complete a "vaccination series," stating medical providers could use the two products "interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns."[5] The FDA website did not address the legal difference between the products, nor was it a determination of biosimilarity or interchangeability, which has specific requirements per 42 USC § 262(k) - Licensure of Biological Products as Biosimilar or Interchangeable. The law cites critical requirements for interchangeable products, including that: 1) a sponsor must submit an application for licensure of the biosimilar product, 2) both products become fully licensed before being declared interchangeable, and 3) per 42 USC § 262(k)7(A), "[a]pproval of an application under this subsection [Licensure of Biological Products as Biosimilar or Interchangeable] may not be made effective by the Secretary until the date that is 12 years after

[3] The approval of Comirnaty® listed the marketing beginning and end date as 23 Aug 2021.
[4] https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF, accessed 10 Aug 2022
[5] https://www fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, accessed 10 Aug 2022

the date on which the reference product was first licensed under subsection (a)." By law, no product may be legally declared interchangeable with Comirnaty® until at least 24 August **2033**. As further evidence, the FDA's authoritative source for approved biologics, the "Purple Book," lists "no interchangeable data at that time" for Comirnaty®.[6] Dr. Adirim, and every military commander who cited her memo as justification for their unlawful orders, ignored the legal distinction between the two products, most notably that one was a licensed product and the other an EUA product, which comes with an inherent right to refuse. This legal distinction was clearly cited by the FDA in every Pfizer BioNTech and Moderna EUA re-issuance letter since full licensure.[7]

10. The DoD cannot claim ignorance with regard to the legal differences between an EUA product and a licensed product that purports to be medically interchangeable but has not become statutorily interchangeable per 42 USC § 262(k). SECDEF statements reflected comprehension of legal requirements associated with EUA products. Additionally, an unsigned memo that was developed by the DoD to replace Dr. Adirim's 14 September 2021 memo, enclosure (4), provided specific guidance that if a service member rejected the EUA product, Health Care Providers should secure and offer the fully licensed product "prior to any punitive action being taken against the Service Member." An official internal review, enclosure (5), provided by reviewers of this memo, demonstrates the subsequent attempt to cover up the DoD's grievous mistake. One comment even acknowledges that this correction "subverts" the current vaccination policy and may open up the service to "increased litigation from individuals who have been mandated since 24 August to be vaccinated." The correction memo was ultimately rejected, demonstrating DoD's awareness and support of illegal prosecution of military members, and a lack of integrity to resolve the situation.[8]

11. When the DOD's unlawful misrepresentation of interchangeability began to fail in federal court, the DoD and DOJ began to allege that the Pfizer EUA vaccine products were compliant with Biologics License Application (BLA) requirements. They coined the term "BLA-Compliant" in an effort to argue that mandating an EUA product was lawful. BLA requirements, however, include an obligation to properly label biologic products. EUA products are not compliant with BLA requirements because the EUA label does not match the BLA approved product label (i.e. Comirnaty®). Senior DoD officials, supported by the DOJ, misrepresented, circumvented, obfuscated, and ultimately violated U.S. law to achieve the unreasonable and detrimental goal of 100% vaccination of the military. Military leadership's disregard for U.S. law has not been limited to vaccines. COVID-19 test kits[9] and masks[10], all of which are EUA products, have been mandated as well.

12. Until May 2022, EUA products were the only COVID-19 vaccines available to the U.S. military. FDA approved vaccines were not available. In spite of this, military leaders coerced and

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[6] https://purplebooksearch fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty, 10 Aug 22
[7] See page 16 of the most recent EUA reissuance letter for an example: https://www.fda.gov/media/150386/download, accessed 10 Aug 2022.
[8] In this same memo, the author admits they are "operating under the belief that the lot issue is a distinction without a difference from a… legal perspective." They also admit that to reverse course and admit "that the distinction does matter would probably require significant remedial actions." See page 5 of enclosure (5) to read these comments.
[9] https://www fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2, accessed 14 Aug 22
[10] https://www fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas, accessed 14 Aug 22

attempted to force administration of EUA products on unwilling service members, pursuing punitive action against many who did not comply. On 20 May 2022, the DOJ filed a memorandum on behalf of the defendants (Austin, et al), enclosure (6), in the Coker v. Austin case in Federal District Court for the Northern District of Florida in which they attempted to undermine the plaintiff's legal standing to challenge in court by asserting that "[w]hile they [the plaintiffs] may believe that FDA-approved vaccines are "not available," the Comirnaty-labeled vaccine is in fact available for DoD to order as of today's date [20 May 2022]." Shortly thereafter, "Comirnaty-labeled" products began appearing in very limited quantities on military installations, including the "Comirnaty-labeled" product seen in enclosure (7). The sudden appearance of "Comirnaty-labeled" vials indicate that the DoD was mandating the use of EUA vaccines for nine months prior to May 2022.

13. In accordance with 21 USC § 360bbb-3(c), the Secretary of HHS may only authorize a product for emergency use if there is no fully licensed product available. The HHS Secretary is further obligated by 21 USC § 360bbb-3(g) to review the progress made by fully licensed products and potentially revoke a product's emergency authorization if a fully licensed product becomes available. If the "Comirnaty-labeled" products identified in enclosure (7) are licensed products, the HHS Secretary should have revoked the various authorizations enabling unapproved EUA biological products to remain on the market. These revocations have not occurred.

14. The status of the new "Comirnaty-labeled" product is also in question. The CDC maintains a database, enclosure (8), of "all lots for COVID-19 vaccines made available under Emergency Use Authorization (EUA) for distribution in the United States."[11] The vial depicted in enclosure (7), which is "Comirnaty-labeled," has the lot number FW1331. This lot number appears in the CDC EUA database as testified by military whistleblower, 1LT Mark Bashaw, per enclosure (9). Misrepresenting an EUA manufactured lot of vaccine product as a fully licensed product is a violation of labeling requirements per 42 USC § 262.

15. Further evidence of potential fraud related to the "Comirnaty-labeled" product pictured in enclosure (7) is Pfizer's admission that the vaccine product with lot number FW1331 was not produced in a BLA approved manufacturing facility. The 16 December 2021 FDA approval letter licensing Comirnaty®, enclosure (10), specifies that the licensed product be manufactured at the Pfizer Manufacturing facility in Puurs, Belgium. Per the testimony provided by LT Coppin in enclosure (11), Pfizer admits that Lot Number FW1331 was actually manufactured in France, not in the approved facility in Belgium. Fully licensed products are required to follow all Biologic License Application requirements. Affixing a "Comirnaty-label" on a product that has not followed all BLA requirements constitutes fraudulent labeling – a federal crime.

16. With regard to fraudulent labeling, 42 USC § 262(b) clearly states that "[n]o person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark." The penalties for such violations are stated in 42 USC § 262(f): "Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment." It is also important to note that fraud voids liability protections and consent agreements. The DoD and its distributed commands (and commanders) may be exposing

[11] Enclosure (8) is the database intro page: https://vaccinecodeset.cdc.gov/LotNumber, accessed 5 Aug 2022

themselves to significant liability by willfully misrepresenting these biologics. Furthermore, as there is no long-term safety data for these products, a link between COVID-19 vaccination and long-term health problems could have a crippling impact on the future readiness of our military. Fraudulent activity and health impacts could result in extraordinary cost to the taxpayer. These challenges add to the DoD's current recruiting and retention crisis brought on by the systemic violation of rights and the destruction of sacred trust with service members.

17. The military is hemorrhaging outstanding military men and women of conscience, who are attempting to defend the rule of law at great personal cost. The DoD has unlawfully discharged thousands of service members for exercising their legal right to decline emergency use products. Ensuring timely DoD adherence to U.S. law requires Congressional action. As the oversight authority, you have the ability to investigate the HHS Secretary's recurring declarations of emergency, as well as potential crimes associated with unlawful administration of EUA products and biologic product labeling fraud. Failure to take swift action will cause continued, irreversible harm to the basic human rights of American citizens while further damaging our national security.

18. Like you, we swore an oath to support and defend the Constitution against all enemies, foreign and domestic. Despite spending our careers focused on foreign enemies, it appears the greatest current threat to our Constitution, to the rule of law, and to U.S. military readiness comes from within. On behalf of service members who share our concerns, as well as the citizens we stand in harm's way to protect, we request that you promptly investigate these matters and hold accountable those found to have acted unlawfully. Please end illegal EUA mandates and all related fraudulent activity to ensure that our military can once again be counted on to uphold the rule of law in support of our Constitution.

Executed on 15 August, 2022.

John S. McAfee
Colonel, USAF

Jon C. Cheek
Lt. Colonel, US Army

Olivia K. Degenkolb
Commander, USN

Robert A. Green Jr.
Commander, USN

David I. Beckerman
Major, USAF

Patrick M. Weir
LCDR, USN

Joshua P. Hoppe
Capt, USMC

Chad R. Coppin
LT, USCG

Mark C. Bashaw
1LT, US Army

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

BENJAMIN COKER, *et al.*,

Plaintiffs,

v.

LLOYD AUSTIN, III, *et al.*,

Defendants.

Case No. 3:21-cv-01211-AW-HTC

DEFENDANTS' MOTION FOR LEAVE TO FILE SUPPLEMENTAL DECLARATION

MOTION

Defendants respectfully request leave to submit the attached supplemental declaration in response to new allegations in Plaintiffs' supplemental filing.

MEMORANDUM

This request is supported by good cause. The Court previously permitted supplemental briefing to apprise the Court of relevant legal and factual developments and to facilitate discussion of these matters at the August 29, 2022 motion hearing. *See* ECF Nos. 105, 106, 107. Among other things, Plaintiffs filed a letter from Senator Johnson containing new allegations about a particular lot of vaccine, FW1331, that Plaintiffs seem to believe may not really be BLA-approved, based on allegations from a service member to the Senator. *See* ECF No. 106-2.

Plaintiffs' filing demanded that Defendants account for "the provenance of these vials." ECF No. 106 at 3.

The proposed filing, attached here, authenticates FDA records showing that Lot FW1331 was manufactured in Michigan (a manufacturing site included in the approved BLA) and was subject to lot release. *See* attached. It is, therefore, indisputably the BLA-approved vaccine Comirnaty, and properly labelled as such. These records thus show that Plaintiffs' newest factual allegations cannot establish standing or refute mootness. It is thus relevant to the jurisdictional issues pending before the Court, and Plaintiffs will have an opportunity to respond at the hearing.

Local Rule 7.1(B) certification: Undersigned counsel provided a copy of the declaration and exhibits to Plaintiffs' counsel and proposed this motion by email on August 24, 2022. Plaintiffs' counsel responded on August 25 that they "are reviewing what you sent but we do not have a position one way or the other at this time."

Dated: August 26, 2022

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ALEXANDER K. HAAS
Director, Federal Programs Branch

ANTHONY J. COPPOLINO
Deputy Director

/s/ *Amy E. Powell*
ANDREW E. CARMICHAEL
AMY E. POWELL
Senior Trial Counsel
STUART J. ROBINSON
Senior Counsel
ZACHARY A. AVALLONE
LIAM HOLLAND
CATHERINE YANG
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, DC 20005
Tel: (919) 856-4013
Email: amy.powell@usdoj.gov

Counsel for Defendants

Local Rule 7.1(F) certification

I hereby certify that this submission contains 271 words, not including the case style, signature block, and certificate of service, according to Microsoft Word's word count function and thus is in compliance with Local Rule 7.1(F).

/s/ *Amy E. Powell*
AMY E. POWELL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA

BENJAMIN COKER, *et al.*, Plaintiffs, v. **LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, *et al.*,** Defendants.	Case No. 3:21-cv-01211-AW-HTC

DECLARATION OF SUZANN BURK

I, Suzann Burk, declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management ("DDOM"), Office of Communication Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland.

2. As the Director of DDOM, I have overall responsibility for the disclosure of documents officially maintained by CBER, the center in FDA that regulates biologic products such as blood, vaccines, gene therapy, and human cells, tissues, and cellular and tissue-based products. I have been the Director of DDOM since June 24, 2018. Prior to that date, I was the Team Lead of the Electronic Disclosure Team in DDOM for approximately nine and one-half years. Prior to that, I was a member of the Congressional and Oversight Branch in DDOM for two years and a member of the Access Litigation and Freedom of Information Branch in

DDOM for four years.

3. In my capacity as Director of DDOM I have access to official CBER documents. I am responsible for disclosing documents in litigation on behalf of CBER.

4. I submit this declaration in support of Defendants' Motion to Dismiss and I understand this declaration may be used in other cases as well. The statements made in this declaration are based on my personal knowledge and official records available to me in my official capacity.

5. Attached hereto as Exhibit 1 is a copy of redacted pages from the lot release protocol for Lot FW1331 of Comirnaty. I certify that Exhibit 1 consists of copies of pages from an official FDA record.

6. I declare under penalty of perjury that the foregoing Exhibit 1 and the facts contained in this declaration are true and correct pursuant to 28 U.S.C. § 1746.

Suzann H. Burk -S Digitally signed by Suzann H. Burk -S
Date: 2022.08.24 11:21:13 -04'00'

SUZANN BURK
Division Director
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

Executed on August 24, 2022

Reason for Submission
For Release

cc: STN 125742-36/2229/FC

Lot Number: FW1331
License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

Formulation: Tris/Sucrose

Manufacturer Name: Pharmacia & Upjohn Company LLC for BioNTech Manufacturing GmbH

Manufacturer Address: 7000 Portage Rd., Kalamazoo, MI 49001 USA

Trade name: COMIRNATY

Date of Manufacturing: 28-Jan-2022 **Expiration Date:** 30-Sep-2022

Fill Information

Container Type:	Vial	**Volume per container:**	2.25 mL
Approved Storage Period:	9 months	**Storage Temperature:**	-90°C to -60°C
Number of containers manufactured:	(b) (4)	**Number of Doses per container:**	10
Number of containers for release:	(b) (4)		
Volume of single human dose:	30 µg/Dose	**Start Date of period of Validity:**	Date of Manufacture

All tests conducted on this lot are reported and pass specifications as required.

Signature: DocuSigned by: R Marty Kenny
Signer Name: R Marty Kenny
Signing Reason: I approve this document
Signing Time: 07-Apr-2022 | 9:53:09 PM EDT
C22F83DD74364E6B9223F89FEC207203

Date: 07-Apr-2022

Title: Manager, Quality Operations
Electronic Protocol # - 20229002.P0

cc: STN 125742-36/2229/FC

Lot Number: FW1331

License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

Formulation: Tris/Sucrose

Manufacturing Site: Pharmacia & Upjohn Company LLC, 7000 Portage Rd., Kalamazoo, MI 49001 USA

Date of Manufacture: 28-Jan-2022 **Date of Expiry:** 30-Sep-2022

Date of Fill: 31-Jan-2022

Product Information:

Drug Substance Target Concentration: (b) (4) mg/mL

COMPONENTS

Component Description	Batch Number	Date of Manuf.	Manufacture Site	Quantity
BNT162b2 Drug Substance	(b) (4)	17-Nov-2021	Pfizer ACMF	(b) (4)
LNP Fabrication and Bulk Drug Product Formulation	(b) (4)	28-Jan-2022	Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Filling/Inspection	(b) (4)	28-Jan-2022	Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Packaging	FW1331	28-Jan-2022	Pharmacia & Upjohn Company LLC	(b) (4)

UNITED STATES SENATE
SENATOR RON JOHNSON
Senate Homeland Security and Governmental Affairs Committee
328 Hart Senate Office Building
Washington, DC 20510

DECLARATION OF 1LT. MARK C. BASHAW IN SUPPORT OF SENATOR RON JOHNSON INVESTIGATION INTO THE SAFETY AND EFFICACY OF COVID-19 VACCINES

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1. My name is 1LT Mark C. Bashaw. I am over 18 years of age, and I am not suffering under any mental disability and am competent to make this declaration under penalty of perjury. I am able to read and write, and I make this Declaration voluntarily and of my own free will and accord. No one has used any threats, force, pressure, or intimidation to make me sign this Declaration, nor has anyone offered or given to me any monetary or non-monetary compensation or reward for making this Declaration. I understand that I am making this Declaration under the penalty of perjury. I have read the statements in this Declaration, and they are my understanding of the facts. Any medical opinion provided in this Declaration is based upon a reasonable degree of medical certainty. I have personal knowledge, experience and understanding of these matters, and I make this Declaration in support of the truth of the contents contained herein.

2. This Declaration is a communication and testimony solicited by and made to a Member of Congress. I make this Declaration as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034.

3. I make this affidavit, as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034, in support of the above referenced MOTION as expert testimony in support thereof.

4. The opinions expressed here are my own and arrived at from my persons, professional and educational experiences taken in context, where appropriate, by scientific data, publications, treatises, opinions, documents, reports, and other information relevant to the subject matter and are not those of the Army or Department of Defense or any component thereof.

5. I am an active duty commissioned Officer in the U.S. Army. I currently serve at the APHC at Aberdeen Proving Ground (APG), Maryland. I serve in the Preventative Medicine (67C) career field and my specialty is Entomology (72B). My official duties include participating in fact-finding inquiries and investigations to determine potential public health risk to DoD personnel from diseases caused by insects and other non-battle related injuries. I received an Associates of Science in Environmental Studies through the Community College of the Air Force (CCAF) in 2010, a Bachelor of Science degree in Management Studies from the University of Maryland, University College in 2013, and a Master of Science in Entomology from the University of Nebraska Lincoln in 2018.

6. I enlisted in the U.S. Air Force on 17 January 2006 and currently have 16 years of total active federal military service (TAFMS). I have served tours overseas to include Japan, Republic of Korea, Germany and multiple deployments to Africa, Middle East, and Central America. I directly commissioned in the U.S. Army Medical Service Corps in September 2019. I initially attended the Direct Commission Course at Fort Sill, OK, followed by the Basic Officer Leadership Course at Fort Sam Houston, TX. I was then stationed at the APHC in January 2020. While at the APHC, I have successfully served as the Headquarters and Headquarters Company (HHC) Commander from May 2020 to July 2021. Currently, I serve in the Entomological Science Division as a Medical Entomologist.

7. My specific duties at the Entomological Science Division within Army Public Health Center (APHC) required that I participate in fact-finding information regarding entomological threats to public health and safety, and properly communicate the risk to our Soldiers. These threats included insect borne diseases, zoological, and other potential non-battle related issues. I also supervised three enlisted Soldiers (Preventative Medicine Specialists, 68S). Additionally, I worked in a mosquito insectary to help with quality checks and standard operating procedures (SOPs). My official duties also include supporting the Army Public Health Program (Army Regulation 40-5) by sustaining the readiness of the force by protecting Army personnel from potential and actual harmful exposures to chemical, biological, radiological, nuclear, and high yield explosive (CBRNE) warfare agents; endemic communicable diseases; food, water, and vector-borne diseases; zoonotic diseases; ionizing and nonionizing radiation; combat and operational stressors; heat, cold, altitude, and other environmental extremes; environmental and occupational hazards; toxic industrial chemicals and toxic industrial materials.

8. Throughout the implementation of the experimental emergency use authorized (EUA) COVID19 mRNA injections, I was aware of enormous safety signals in the Centers for Disease Control's (CDC) Vaccine Adverse Event Reporting System (VAERS). In September and October of 2021, I started communicating these concerns to the Army Public Health Center COVID19 Task Force to get the Risk Communication Strategy changed to include the concerning VAERS data and frontline doctor testimony. I was ignored. Shortly thereafter, I was targeted for not participating with COVID19 experimental emergency use authorized products (masks, tests, and mRNA injections). I was then charged with Article 92 UCMJ and sent to a Special Court Martial (United States v 1LT Mark Bashaw) on 28-29 April 2022. I was convicted and sentenced to "no additional punishment" by the Judge. I explained throughout the court martial that these COVID19 experimental EUA products are dangerous and deadly. I also gave testimony regarding my initial and formal Article 138 UCMJ complaint that was initiated on 26 November 2021 against my commander, after I was unlawfully discriminated against on 23 November 2021.

9. On 29 July 2022, I registered for a CDC Vaccine Lot Number and Expiration Date Report Account. Within the DOD and USCG, there have been questions with certain "Comirnaty Labeled" vial lots that have been showing up on base medical clinics. Many medical personnel and commanders around the DoD and USCG have been claiming these are the FDA Approved and Licensed vials. **However, these lot numbers are listed on the CDC's Emergency Use Authorized (EUA) COVID19 Lot Listing.**

10. The following is an excerpt from the CDC's COVID-19 Vaccine Lot Number and Expiration Date Report Database, **"These files contain all lots for COVID-19 vaccines made available under Emergency Use Authorization (EUA) for distribution in the United States. The downloadable file includes the manufacturer, the National Drug Codes (NDCs) for Unit of Sale (boxes/cartons) and Unit of Use (vials) for each lot number, and the manufacture date and expiration date."**

11. Using the CDC's database, I was able to verify that the "Comirnaty Labeled" vials with **lot number FW1331**, that has shown up on various U.S. military and U.S. Coast Guard bases (Whistleblower Declaration: LT Chad Coppin, USCG, 30July2022), **is listed on CDCs COVID-19 Vaccines under Emergency Use Authorized (EUA) List.** There's obviously confusion as to why experimental COVID19 EUA vials are still being manufactured and new EUA authorizations are being granted (i.e., NOVAVAX), if we have a "supposed" fully FDA Approved and Licensed vials available. There's also confusion as to why this alleged fully FDA Approved and Licensed product is on the CDC's official EUA Lot Listing.

12. As of 22 July 2022, there have been 29,790 deaths from these experimental EUA COVID19 injections and 1,357,940 adverse injuries, according to the CDC's VAERS data. There's also been 1,000 peer review studies about the adverse injuries related to these experimental EUA COVID19 injections (https://community.covidvaccineinjuries.com/compilation-peer-reviewed-medical-papers-of-covid-vaccine-injuries/). Additionally, on 06 January 2022, a federal court ordered the FDA to release the COVID19 vaccine documents. It was these documents that the FDA relied heavily on to facilitate a fully FDA Approved and Licensed COIVID19 injection. These documents also corroborate the concerning safety signals.

13. Important to note that "Covered Persons" (i.e., U.S. Government, manufacturer, distributor….) with respect to administration or use of a "covered countermeasure" (i.e., EUA COVID19 mRNA injections, masks, and tests) "shall be immune from suit and liability…. (Title 42 U.S.C. Section 247d-6d [a] [1])." Also, Title 21 U.S.C. 360bbb-3 has important "Required Conditions" associated with EUA products and Title 10 U.S.C. section 1107a has important requirements, specifically for Service Members. **According to Army FRAGO 5, "Commanders will ensure sufficient doses of Department of Defense Approved vaccines are on hand and available for their unit. Soldiers may at any time still voluntarily receive any other vaccine approved for emergency use." Again, according to the CDC lot listing, the only vial lots that exist are under emergency use authorization.** Therefore, required conditions such as, the right to accept or refuse participation with such EUA products is a **REQUIRED CONDITION** per Title 21 and Title 10 sections listed above.

14. To date, there are no available FDA Approved masks and tests for the prevention and/or detection of COVID19 (SARS-CoV-2), they are all EUA and fall under the same federal statutes listed above. These EUA products have been weaponized against individuals who lawfully chose not to participate with the experimental EUA COVID19 injections. However, everyone has the right to accept or refuse such experimental EUA products without fear of reprisal, again, according to the federal statutes above. However, Commanders around the DoD are initiating reprisal against their Service Members. This is an unlawful practice.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: 04 August 2022
Signature:

Mark C. Bashaw, 1LT/MS

Maryland State
Anne Arundel County

On 08/04/2022 date before me, as Notary and as Jurat Certificate of Acceptance by court officer, Mark Charles Bashaw personally appeared and proved to me on the basis of satisfactory evidence to be the man whose Name is subscribed to the within attached instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his autograph on the instrument the man executed, the instrument.

I certify under PENALTY OF PERJURY under the lawful laws of Maryland State and the STATE OF MARYLAND that the foregoing paragraph is true and correct Witness my hand and official seal.

Signature _____ seal
of Notary Republic

David A. Chiodaroli
NOTARY PUBLIC
Anne Arundel County
MARYLAND
MY COMMISSION EXPIRES August 11, 2025

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0 **BLA APPROVAL**

BioNTech Manufacturing GmbH August 23, 2021
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts. The final formulated product will be manufactured, filled, labeled and packaged at Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium and at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at Hospira, Inc., (b) (4) and at Fresenius Kabi USA, LLC, (b) (4) .

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90ºC to -60ºC (-130ºF to -76ºF). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at Pharmacia & Upjohn Company LLC in Kalamazoo, Michigan, the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer Manufacturing Belgium NV in Puurs, Belgium, it is defined as the date of the (b) (4) Following the final sterile filtration, (b) (4) , no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4) We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

   Final Protocol Submission: February 8, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.
Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

5. Study C4591021, entitled “Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: January 31, 2022

   Study Completion: March 31, 2024

   Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June 30, 2022

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”

    Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

    Final Protocol Submission: September 30, 2021

    Study Completion: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion: June 30, 2023

    Final Report Submission: December 31, 2023

13. Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."

    Final Protocol Submission: March 22, 2021

    Study Completion: December 31, 2022

    Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/36 **SUPPLEMENT APPROVAL**

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

December 16, 2021

Dear Mr. Patel:

We have approved your request submitted and received on November 18, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), to include a new 30 microgram dose formulation (Tris/Sucrose) of COMIRNATY manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs) facility.

LABELING

We hereby approve the draft content of labeling including the Package Inserts submitted under amendment 10, dated December 13, 2021, and the draft carton and container labels submitted under amendment 6, dated December 9, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Inserts submitted on December 13, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on December 9, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125742, at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Our STN: BL 125742/45

SUPPLEMENT APPROVAL
PMR FULFILLED

BioNTech Manufacturing GmbH
Attention: Gosia Mineo, M.S.
Pfizer, Inc.
1 Pfizer Way 190/004/4405
Pearl River, NY 10965

July 8, 2022

Dear Ms. Mineo:

We have approved your request received on December 16, 2021, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs), Pharmacia & Upjohn Company LLC, Kalamazoo, Michigan (Pfizer, Kalamazoo) and Hospira, Inc., McPherson, Kansas (Pfizer, McPherson) facilities, to include use in adolescents 12 through 15 years of age for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The review of this supplement was associated with the following National Clinical Trial number: 04368728.

LABELING

We hereby approve the draft content of Package Insert labeling, submitted under amendment 13, dated July 1, 2022.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on July 1, 2022. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN 125742, at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

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All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfills your postmarketing requirement #1 identified in the August 23, 2021, approval letter for BLA STN 125742/0 for COVID-19 Vaccine, mRNA. The requirement addressed in this submission is as follows:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: October 31, 2023

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for ages 12 through 15 years for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Doran Fink, M.D., Ph.D.
Acting Deputy Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research